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DEPARTMENT OF ENERGY

10 CFR PART 830 Nuclear Safety Management Docket No. NE-RM-91-830 RIN 1901-AA34

10 CFR PART 834
Radiation Protection Of The Public And The Environment Docket No. EH-RM-93-834
RIN 1901-AA38

AGENCY: Department of Energy

ACTION: Notice of limited reopening of comment periods.

On December 9, 1991, the Department of Energy (DOE) SUMMARY: published a Notice of Proposed Rulemaking to add regulations establishing a body of rules for DOE contractor and subcontractor activities to ensure safe operation of DOE's nuclear facilities. On March 25, 1993, DOE published a Notice of Proposed Rulemaking to add regulations establishing standards for the protection of the public and the environment against radiation from DOE The purpose of this notice is to reopen the comment acti vi ti es. periods in these two rulemakings for 30 days in order to solicit comments on options now being considered in light of (1) public comments received during the initial comment periods, (2) comments received from the Defense Nuclear Facilities Safety Board (DNFSB), and (3) comments raised in connection with Departmental initiatives concerning the management of the DOE This notice also announces the availability of current complex.

draft language for these regulations, as well as a draft discussion of the regulatory system under development by DOE.

DATES: Written comments (11 copies) on the issues presented in this notice must be received by the Department on or before [insert date 30 days from publication].

ADDRESSES: Part 830: Written comments on Part 830 (11 copies) should be addressed to PART 830, Mr. Orin Pearson,

U. S. Department of Energy, Office of Environment, Safety and Health, EH-10, Forrestal Building, 1000 Independence Avenue, S. W., Washington, D. C. 20585.

Part 834: Written comments on Part 834 (11 copies) should be addressed to PART 834, Mr. Andrew Wallo, U.S. Department of Energy, Office of Environment, Safety and Health, EH-412, 1000 Independence Avenue, S.W., Washington, D.C. 20585.

Public Reading Room: Copies of the December 9, 1991 Notice of Proposed Rulemaking, written comments received on the December 9, 1991 Notice, and current draft regulatory language for 10 CFR Part 830 are contained in Docket No. NE-RM-91-830. Copies of the March 25, 1993 Notice of Proposed Rulemaking, written comments received on the March 25, 1993 Notice, and the current draft regulatory language for 10 CFR Part 834 are contained in Docket No. EH-RM-93-834. These docket are available for examination in DOE's Freedom of Information Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 586-6020, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Internet: The draft regulatory language for Part 830 and for Part 834, as well as the draft discussion of the regulatory system under development, is available on the internet at "gopher: //nattie.eh. doe: gov: 2011/11/. Drafts".

FOR FURTHER INFORMATION CONTACT:

Part 830: Mr. Richard Stark, U.S. Department of Energy, Office of Environment, Safety and Health, EH-31, 19901 Germantown Road, Germantown, Maryland 20874-1290, (301) 903-4407.

Part 834: Mr. Andrew Wallo, or Mr. Harold T. Peterson, Jr., U.S. Department of Energy, Office of Environment, Safety and Health, EH-412, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 586-2409, fax (202) 586-3915.

Written Comments: Ms. Andi Kasarsky, (202) 586-3012.

SUPPLEMENTARY INFORMATION:

Background:

On December 9, 1991, the Department published a Notice of Proposed Rulemaking (56 FR 64316) to add a new part (10 CFR 830) to its regulations establishing a body of rules for DOE contractor and subcontractor activities to ensure safe operation of DOE's nuclear facilities. The proposed rule contained nine specific sections covering (1) safety analysis reports, (2) unreviewed safety questions, (3) quality assurance requirements, (4) defect identification, (5) conduct of

operations, (6) technical safety requirements, (7) training, (8) maintenance, and (9) operational occurrences, as well as general provisions for the application of these rules. A public hearing was held on February 25, 1992 in Germantown, Maryland and the 60-day comment period closed on March 25, 1992. A final rule on the quality assurance requirements and the general provisions for their application was published in the Federal Register on April 5, 1994 (59 FR 15843). The rulemaking remains open with respect to all areas other than the quality assurance requirements.

On March 25, 1993, the Department of Energy (DOE) published a Notice of Proposed Rulemaking (58 FR 16268) to add a new part (10 CFR Part 834) to its regulations establishing standards for the protection of the public and environment against radiation. The requirements would be applicable to the control of radiation exposures to the public and to the environment from normal operations under the control of DOE and DOE contractor personnel. The March 25, 1993 Notice described the four basic elements of the radiation protection system it proposed to implement for protection of the public and environment:

- (1) Establish dose limits for exposure of members of the public to radiation and implementation of the Department's "as low as is reasonably achievable" (ALARA) policy;
- (2) Manage radioactive materials in liquid waste discharges, in soil columns, and in selected solid waste

containing radioactive materials, including a ground water protection program for each DOE site;

- (3) Establish requirements for decontamination, survey and release of buildings, land, equipment, and personal property containing residual radioactive material and the management, storage and disposal of wastes generated by these activities; and
- (4) Establish an Environmental Radiation Protection Program (ERPP) and plan (including an effluent monitoring and environmental surveillance program) to set forth the programs, plans, and other processes to protect the public from exposures to radiation.

A public hearing was held on May 13, 1993 in Germantown, Maryland and the 60-day comment period closed on June 22, 1993. The rulemaking remains open with respect to all areas.

The Department has considered (1) public comments received during the initial comment periods on Part 830 and on Part 834,

(2) comments received from the Defense Nuclear Facilities Safety Board (DNFSB), and (3) comments raised in connection with Departmental initiatives concerning the management of the DOE complex. As a result of this consideration, the Department has refined its views concerning the objectives and operation of the regulatory system which will include Part 830 and Part 834.

In general, the public comments received during the initial comment period relate to the details of the proposed rules and the scope of their coverage. They also raise questions

concerning (1) the transition from the requirements in existing DOE Orders, (2) implementation of the rules, and (3) compliance with the rules.

The DNFSB has commented on numerous occasions on the relationship between the proposed rules and the establishment of a standards-based safety program at the Department. For example, in Recommendation 94-5 the DNFSB called for the Department to integrate its development of safety rules, orders, and other requirements into an integrated safety management program and, in particular, expressed its concern that the process of converting DOE Orders to rules not be used as an occasion to (1) unduly relax or eliminate important nuclear safety requirements in Orders, (2) relegate good nuclear safety practices extant in existing Orders to optional status, or (3) forego or delay current efforts to bring safety practices into compliance with mutually-agreed implementation plans that respond to recommendations of the Board.

In 1993, Vice President Gore established the National Performance Review to evaluate the operation of the Federal Government and make recommendations on how to reduce the cost and increase the efficiency of government. In its report on improving regulatory systems, the National Performance Review made several recommendations on achieving regulations that are effective, consistent, sensible, and understandable. In general, these

recommendations encourage innovation, cooperation, public involvement and the use of existing commercial standards, while discouraging "command and control" approaches.

In addition to the National Performance Review, there have been several initiatives concerning management of the DOE complex. For example, the Galvin Commission examined alternative futures for the national laboratories. In general, the Galvin Commission found that the Department currently micromanages the laboratories and recommended that the laboratories be run as a corporation to the extent practicable. In the alternative, the Commission recommended changes to the current system, including

(1) replacement of compliance-based directives with simple, well-defined performance measures, (2) elimination of approval by the Department of the laboratories' internal procedures, and

(3) operation of the laboratories according to industry-wide regulatory standards.

In response to the National Performance Review and initiatives concerning the management of the DOE complex, the Department has conducted an extensive review of the system of safety standards for its nuclear facilities, including the proposed rules in Part 830 and Part 834, to determine the extent to which this system (1) emphasizes performance and (2) empowers those most affected by the system to play a major role in deciding how an adequate level of performance is achieved. In conjunction with this

review, the Department has undertaken several specific actions, including (1) the Directives Reduction Initiative and (2) the development of the "necessary and sufficient" process.

As part of the Directives Reduction Initiative, the Department is reviewing existing DOE Orders to decide which of the provisions therein should be retained as requirements or as guidance concerning acceptable implementation methods. The Department also is considering the extent to which requirements should be modified to provide clear performance standards. The Department intends to issue revised DOE Orders to set forth those nuclear safety requirements that it decides to retain, except for those requirements that are contained in DOE rules already issued or The Directives Reduction Initiative has generated proposed. comments on the proposed rules because many of the provisions in the existing Orders cover the same subject matter as the proposed rul es.

The Department is developing the "necessary and sufficient" process to permit the Department, its contractors, and other interested parties to work as partners in determining the requirements, standards, and implementing actions that, taken together, will ensure an adequate level of protection for a particular facility or activity, taking into account the hazards associated with that facility or activity and other relevant factors. The necessary and sufficient process is intended to

move away from the "one size fits all" approach towards a tailored approach that recognizes the differences among the diverse DOE facilities that can range from an accelerator to a research reactor to a weapons dismantlement plant to a clean-up site. When fully developed, the necessary and sufficient process will provide a better way of ensuring adequate protection by assessing the work to be performed, analyzing the hazards involved, and then determining the requirements and implementing procedures, programs, plans and other actions that are "necessary and sufficient" to address those hazards. The development of the necessary and sufficient process has generated comments concerning the intended relationship between the operation of that process and the proposed rules.

REQUEST FOR COMMENTS

The Department is issuing this notice to solicit comments from the public on issues raised by the comments and options under consideration to respond to these comments. In connection with the reopening of the comment periods, the Department is making available to the public draft regulatory language for Part 830 and for Part 834 currently under consideration. The Department also is making available a draft discussion of the regulatory system which will result from the Department's current rulemaking activities. These draft documents do not represent a final

position of the Department, but are being made available to assist in the formulation of comments.

In particular, comments are solicited on the following topics.

PART 830

- 1. Detailed requirements versus performance objectives
- Much of the discussion concerning the proposed Part 830 rules has focused on whether the proposed rules should be revised to contain more of the detailed requirements in the existing Orders or whether some of the proposed rules are too detailed and should be revised to focus on performance objectives. Those comments that favor more detailed requirements should specify the requirements to be added and the reasons why a particular requirement should be imposed uniformly throughout the DOE complex. Likewise, those comments that favor requirements more in the form of performance objectives should describe such objectives in sufficient detail to permit an evaluation of the extent to which they are sufficient to ensure adequate protection of workers, the public, and the environment.
- 2. Exclusion of below hazard category 3 facilities. Many comments related to whether the nuclear safety management requirements of Part 830 should cover all nuclear facilities, especially those below hazard category 3. The Department is

considering an option that would respond to these comments by excluding nuclear facilities below hazard category 3 from the scope of Part 830. Comments also might consider the extent to which specific requirements in Part 830 are needed for hazard category 2 or 3 facilities. It should be noted that the exclusion of certain facilities from the requirements of Part 830 is not intended to affect their coverage by the radiation protection requirements of 10 CFR Part 834 and 10 CFR Part 835, Occupational Radiation Protection. These requirements would assure that workers, members of the public, and the environment are adequately protected from the harmful effects of radiation.

In commenting on this option, consideration should be given to whether the hazard categories in DOE Standard 1082-92 should be incorporated as definitions in Part 830 and, in particular, whether the description of hazard category 3 in DOE Standard 1082-92 is more appropriate than the description of hazard category 3 in the Notice of Proposed Rulemaking. In considering the use of the definitions in DOE Standard 1082-92, attention should be given to the potential effect on the portion of the definition of nonreactor nuclear facility that includes activities or operations relating to the design, manufacture, or assembly of items for use with radioactive materials and/or fissionable materials in such form or quantity that a nuclear hazard potentially exists. This portion of the definition of nonreactor nuclear facility covers activities where no nuclear

material is present (such as activities at facilities that prepare the nonnuclear components of nuclear weapons or that assemble or manufacture safety related equipment for nuclear facilities), but which could affect activities in facilities where nuclear material is present.

- 3. **Transportation.** Some comments on the scope of Part 830 relate to the coverage of transportation in light of the exclusion of transportation activities from the definition of nonreactor nuclear facilities. This exclusion is intended to avoid regulatory duplication since most transportation of radioactive materials occurs off site where it is typically governed and regulated by agencies other than the Department. DOE is considering responding to the comments by (1) deleting the exclusion of transportation activities from the definition of nonreactor nuclear facilities and (2) excluding from the scope of Part 830 those transportation activities governed and regulated by either the U.S. Department of Transportation, the national security provisions of 49 CFR 173.7(b), or the U.S. Nuclear Regulatory Commission.
- 4. Weapons program. Some comments requested clarification of the exclusion of activities relating to the prevention of accidental or unauthorized detonations of nuclear weapons. This exclusion is drafted narrowly to cover only those activities whose purpose is to prevent nuclear detonations (that is, where

the component parts of a nuclear weapon have been assembled in a manner such that a nuclear detonation could take place). basis for this exclusion is the paramount importance of preventing accidental or unauthorized nuclear detonations and ensuring that the regulatory requirements in Part 830 do not come into conflict with activities necessary to prevent any such detonation. These exclusions do not relieve the person responsible for a DOE nuclear facility from complying with regulatory requirements to the extent they do not interfere with the conduct of activities undertaken to prevent a nuclear detonation. The Department is considering an option to incorporate this clarification explicitly in the regulatory I anguage. Comments on this issue also should consider an option under which the exclusion would be eliminated, but which would make clear safe management requirements must be tailored to take into account the paramount importance of preventing accidental or unauthorized detonations.

5. Offsite coverage. Some comments relate to the coverage of activities that do not occur at a DOE nuclear facility. For example, many training, maintenance, and quality assurance activities are conduct outside the facility to which they relate. The Department is considering responding to these comments with an option that would expand the scope of Part 830 to cover conduct that could affect the safe management of nuclear

facilities without any limitation that such conduct must occur at nuclear facilities.

- 6. Coverage of DOE employees and DOE operated facilities. Some comments question why the scope of Part 830 does not extend to DOE employees and to facilities operated by the Department (and not by a contractor). The Department is considering responding to these comments with an option that would modify the scope of Part 830 to cover DOE employees and DOE operated facilities in the same manner as Part 835.
- 7. Coverage of nonradioactive hazards. Some comments have questioned the extent to which the proposed rules relate to chemical or other nonradioactive hazards. These comments point out that some of these hazards have the ability to (1) cause or exacerbate accidents involving the release of radioactive material, (2) reduce the level of nuclear safety and/or (3) have a significant affect on the hazard level of the facility. considering options under which the rules would address (1) only radioactive hazards at a nuclear facility, (2) only radioactive hazards and those hazards which could cause or exacerbate an accident involving radioactivity or reduce the level of nuclear safety, or (3) all hazards which could present a substantial safety hazard at a nuclear facility. Comments on this issue should indicate what changes, if any, might be needed to the proposed rules to accommodate the option favored by a comment.

- 8. Applicability to non-nuclear facilities. Some comments have suggested that the scope of the proposed safety management rules in Part 830 be extended to non-nuclear facilities. These comments point out that many DOE sites have nuclear and nonnuclear facilities and that many of the rules (e.g., training) could be applicable to both nuclear and non-nuclear facilities and thus result in integrated and coordinated site-wide safety management programs that would be more efficient and effective. The Department is considering responding to these comments with an option to make the language in some of the rules in Part 830 more general and applicable to non-nuclear, as well as nuclear This option would not expand the scope of Part 830 facilities. beyond DOE nuclear facilities or subject non-nuclear facilities to the procedural and enforcement requirements delineated in This option would permit the Department, however, to Part 820. impose contractually the relevant requirements in Part 830 on non-nuclear facilities and thus result in a more uniform and coordinated safety program for a site.
- 9. Implementation plans. Implementation plans were the subject of many comments. These comments related to (1) the timing of their submission and effectiveness, (2) the possibility of integrating the plans for a facility or site, (3) the relationship to the necessary and sufficient process under development, (4) the relationship to Standards/Requirements

Identification Documents (SRIDs) and Order compliance activities, and (5) the relationship to the authorization basis. In response to these comments, the Department is considering options to clarify the role of implementation plans and to make them a more effective tool for cooperation between the Department and its contractors.

10. Compliance. Some comments concerned the manner in which the Department would evaluate compliance with the regulatory requirements in Part 830. The Department is considering options to make clear that compliance with regulatory requirements will be evaluated in terms of (1) a hazard analysis of the work to be performed, (2) the identification of standards and other actions appropriate for the hazards in a particular workplace, (3) the application of those standards and actions to the workplace, and (4) the obligation for ongoing self-assessment.

PART 834

1. Detailed requirements versus performance objectives. Some comments suggested the proposed rules should be revised to contain more detailed requirements, while other comments indicated the proposed rules are too detailed and should be revised to focus on performance objectives. In general, the Department believes it has balanced these concerns to ensure that the requirements established in the rule include those that are necessary to ensure protection of the public and environment from

hazards associated with radioactive material and are sufficiently flexible to afford cost effective implementation. In particular, the Department's application of the "as low as reasonably achievable" (ALARA) process to permit individual operations to select site specific goals and appropriate means of achieving them in a manner that considers social, technical, economic, practical and public policy considerations along with dose reduction provides flexibility to address site specific factors and avoids the "one size fits all" concept. The adoption of specific dose limits below which the ALARA process operates provides added assurance that the rules are protective.

Those comments that favor the addition of more detailed requirements should specify the requirements to be added and the reasons why a particular requirement should be imposed uniformly throughout the DOE complex. Likewise, those comments that favor requirements more in the form of performance objectives should describe such objectives in sufficient detail to permit an evaluation of the extent to which they are sufficient to ensure adequate protection of workers, the public, and the environment.

2. Organization of the draft final rule. In response to public comments, the Department is considering revising the structure of the rule to make the presentation easier to follow. The Department also is considering whether definitions should be

added, revised or deleted for consistency and to eliminate ambiguity.

- 3. **Demonstrating compliance with dose limits**. The primary dose limit of 100 mrem is based on all sources of radiation. demonstrate compliance with dose limits, the rule requires evaluations of doses to members of the public who live in or occupy an area most likely to receive the highest doses. requires consideration of the likely exposure pathways through air, water, food, and surfaces of property and the location of Doses from radiation sources other than those those sources. from DOE activities must also be evaluated. DOE is considering modifying the proposed rule to require evaluation of doses from non-DOE activities only when: (1) the dose from DOE activities exceeds 30 mrem in a year, and, (2) the dose from the non-DOE activities also exceeds 30 mrem in a year to the same i ndi vi dual s. This allocation of the primary dose limit to different sources of radiation exposure is consistent with national and international guidelines and is a practical approach which ensures that the primary dose limit will likely not be exceeded.
- 4. Doses from Accidental Releases of Radioactive Materials.

 Some commenters were concerned with the application of the Part 834 dose limits to accidents. The Department is considering deleting § 834.9 of the proposed rule which resulted in

confusion. The proposed rule was unclear as to whether and when these doses were subject to the dose limits. The Department is considering clarifying the applicability of the dose limits by adding § 834.1(b) stating "The public dose limits in this rule are intended to apply to doses to members of the general public from routine operations and operational occurrences. The dose limits are not intended to be safety design criteria or guides for mitigating the consequences of accidents." DOE would continue to require that doses from accidents be evaluated and reported.

- 5. Requirements Applicable to Liquid Sources of Radioactive
 Materials---Liquid Discharges. The Department is considering an option to clarify that stormwater runoff and purge water containing residual radioactive material are considered to be liquid waste streams. Moreover, to reduce dual regulation, the Department is considering an option to allow DOE activities operated in accord with a National or State Pollution Discharge Elimination System permit to be exempt from selected requirements.
- 6. Discharges of liquid waste to aquifers and phaseout of soil columns. The proposed rule provided for discontinuance of existing soil columns and the prohibition or increased discharges to soil columns. The Department is considering an option that would provide for exceptions where the discharges to the soil columns are treated by the Best Available Technology (BAT) and

would result in less risk to the public and the environment than any other practicable alternative waste management practice.

This process would allow case-by-case exceptions, include requirements to ensure the National Primary Drinking Water regulations are not exceeded, and require monitoring of actual concentrations in the soil column and aquifers.

- 7. Discharges to sanitary sewerage. The Department is considering an option to make its requirements for discharges to sanitary sewerage more consistent with the NRC requirements on discharges of radioactive materials from NRC-licensed facilities in § 20.2003 of 10 CFR Part 20. This option would limit the released material to dissolved or dispersible biologic materials.
- 8. Radiation Protection of Aquatic Organisms. As proposed, Part 834 contained requirements for the protection of aquatic organisms. Some commenters were concerned about implementation of the 1 rad per day aquatic limit. There was concern with the difficulty and cost associated with adequately defining dose to organisms in an exposed population. DOE is considering establishing a screening criterion to simplify the demonstration of compliance. If it can be shown that the estimated dose to a representative individual of an exposed population is less that 0.1 rad per day, then compliance with the primary aquatic limit may be assumed; otherwise more detailed analyses are needed. The

Department is seeking comments on the use of this screening criterion.

9. Appended Guides. The Department is considering omitting the tables of Derived Concentration Guides (DCGs) appended to the proposed rule as Appendix A in order to permit periodic revision of the information found in the appendix. This option would require that DCG values and other factors be taken from DOE-approved references or calculated by DOE-approved methods.

The Department urges interested members of the public to comment on the important issues discussed above.

Issued in Washington, DC on August 28, 1995

Peter N. Brush

Principal Deputy Assistant Secretary

Environment, Safety and Health